R E M A R K S

All rejections have been considered and are addressed in the amendments set forth above and the remarks which follow in order to overcome all objections and rejections and bringing the application into condition for allowance at this stage of prosecution. Claims 1-18 have been cancelled and replaced by claims 19-63. New claims 19-43 are directed to an intraocular lens and new claims 44-63 are directed to a process for making an intraocular lens. The new claims include dependent claims reciting subject matter disclosed in the specification but not previously claimed.

Claims 12-18 (corresponding generally to new claims 44-52) were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims have been reviewed and all points of indefiniteness addressed in the amendments proposed for entry. It is submitted that all points of indefiniteness have been overcome and the claims are fully in compliance with 35 U.S.C. 112, second paragraph.

Claims 1, 2, 4, 5, 8-18 (corresponding generally to new claims 19-20, 23, 24, 29-32 and 44-52) were rejected

under 35 U.S.C. 102(b) as being anticipated by Vanderbuilt US No. 5,326,506.

Claim 1 has been cancelled and replaced by new claim 19. According to new claim 19, it is provided an intraocular lens which is comprised of a flexible material. The intraocular lens has at least one relatively rigid portion, the flexible material having a structural modification to impart rigidity.

As acknowledged in the introduction of the present application, bimaterial intraocular lenses are known in the art. Such lenses involve the fusion or assembly of the respective parts of the lens, typically the haptic and optic parts. Prior art bimaterial intraocular lenses do not inherently ensure structural integrity and involve either bonding, fusion and/or assembly steps. The prior art cited is representative of such known teachings and fails to teach or suggest the present invention.

Indeed, in none of the cited and applied prior art is there disclosed an intraocular lens or other type of optical device comprising both flexible material and rigid material in which the relatively rigid material comprises a structural modification of the flexible material to impart rigidity. The present intraocular lens is thus comprised of a flexible base material with portions having structural modifications imparting

relative rigidity, as opposed to separate or additional portions which are bonded, fused or otherwise assembled.

Reference is now made to Vanderbuilt which discloses a one-piece composite lens having a soft, foldable central optic region and a hard non foldable outer peripheral region making up the haptics or legs of the intraocular lens. The Vanderbuilt invention is directed to a method of strongly joining together two dissimilar polymer materials, so that a one-piece foldable IOL may be lathed from the composite material disc. The soft optical region is a p-HEMA or a copolymer thereof. The peripheral hard material is PMMA or a copolymer thereof.

The methods disclosed in Vanderbuilt comprise cutting discs from a rod into an intraocular lens. The discs may be made by polymerizing HEMA or HEMA and HOHEXMA possibly by adding a crosslinking agent. In one method, the disc is centered in a larger diameter mould and a polymerizable liquid is poured into the mould and cured whereupon the polymerizable liquid becomes the hard outer polymer segment in contact with the core. If the polymerizable liquid does not soften or penetrate the core material, no bonding takes place at the interface and therefore bonding can be effected by pre-swelling the core material which is miscible with the polymerizable

outer liquid. According to a third method, the composition of the rod is altered so that the polymerizable outer liquid will swell and penetrate the core. This is accomplished by adding a co-monomer to the co-monomer which will ultimately become the soft core rod.

In all cases, bonding is effected between the soft foldable material of the central core and the polymerizable material at the periphery thereof. In no case is the portion or portions of relatively rigid material a structural modification of the flexible material, as recited in new claim 19. The claimed invention provides a considerable advantage over the prior art by avoiding the need of bond, fuse or otherwise assemble two distinct polymeric materials disclosed in the art exemplified by Vanderbilt.

With regards to original claims 2-6, not all of which were rejected, in particular claims 3 and 6, column 5, lines 59-68 were cited. Claims 2-6 correspond generally to new claims 19-25. While it is true that Vanderbilt does indeed teach a flexible material made of cross-linked polymer and copolymer materials, which may be cross-linked by a functional agent, as noted above, this patent is silent as to a chemically structurally

modified flexible material defining relatively rigid material.

With respect to claims 8-10 (corresponding to new claims 26-29), column 7, lines 61-68 and column 8, lines 1-12 were cited. The comments made with respect to claims 2-6 is likewise applicable here. Further, there is no teaching or suggestion in Vanderbilt of an optic part comprising one or more portions of flexible material and one or more portions of rigid materials. Given the method of preparation of Vanderbilt's intraocular lenses, it would be virtually impossible to produce an optical part with portions or alternating strips of rigid material. Nor would one having ordinary skill in the art thought of doing so, since it is ostensibly counter-indicated as the optic disclosed in this patent is made of entirely flexible material, so that it can be folded.

As regards claim 30 (corresponding generally to original claim 9), there is clearly no teaching or suggestion in Vanderbilt of having a structural continuity between rigid material of the optic part and rigid material of the haptic part. For one, the optic part in the Vanderbilt intraocular lens includes no rigid material and second there can be no structural continuity with the rigid material of the haptic part and the rigid material of the optic part.

New claim 31 is patentable by reason of its dependency from claim 19.

As regards the process claims 44-63, they are clearly not taught or suggested by Vanderbilt, specifically Vanderbilt fails to disclose selectively modifying the flexible material of the pre-form to define at least one portion of relatively rigid material of the ultimate intraocular lens. Indeed, as abundantly noted above, Vanderbilt uses bonding including swelling to add the rigid material to the central core of flexible material.

Claims 1-4, 7-18 (corresponding generally to new claims 19-23 and 26-44) were also rejected under 35 U.S.C. 102(b) as being anticipated by Bos et al, US 5,762,836. The teachings at column 11, lines 24-29 and column 12, lines 32-34 were specifically relied upon.

Bos et al disclose a method of making an intraocular lens having a haptic portion of a first flexible material and a haptic portion of a second rigid material. A mold is provided and a plate of the second material with a central recess not less than the diameter of the haptic portion is positioned in the mold and the first material in liquid form is introduced in the mold between the mold part and the volume bonded by the recess in the plate of the second material and thereafter cured and unmolded.

Various measures are taken to compensate for the shrinkage of the first material (see the Summary of the Invention of Bos et al).

Depending on the nature of the first and second materials, they may be bonded by extensions into the central recess which form inserts which are embedded into the optic or lens portions. Alternatively, the first and second materials are selected so as to achieve bonding by interpenetration of the networks of these materials. It is specifically noted (column 5, lines 8-9) that the interpenetration should not alter the stiffness. According to another embodiment, the periphery of the central recess of the plate is prepared to achieve adhesion between the first and second material during molding. Finally, it is noted that these different embodiments may be used separately or in combination (see column 4, lines 66 through column 5, line 20).

Clearly, there is no teaching or suggestion in this reference of structurally modifying flexible materials which define the relatively rigid material of an intraocular lens. Quite the contrary, all embodiments involve bonding, fusion or adhesion in order to secure the rigid material to the flexible material. From the viewpoint of the present invention, the Bos et al

technology is not different from the Vanderbilt technology.

It is therefore beside the point that the flexible material disclosed in Bos et al may be hydrophilic. It is similarly of no import that Bos et al disclose polymer materials such as polydimethylsiloxane suitable for use in an intraocular lens. What distinguishes the present invention from the prior art is not the specific polymer material recited in claims but rather portions of that specific material have a structural modification which define the relatively rigid material.

In view of the foregoing, it appears not necessary to discuss in detail the claims directed to an intraocular lens or the process of making such a lens which cannot be derived from teachings of Bos et al.

Claim 6 (corresponding to new claim 25) was rejected under 35 U.S.C.103(a) as being unpatentable over Vanderbuilt in view of Freeman US 5,693,095.

The Examiner acknowledges that Vanderbilt fails to disclose diethylene glycol dimethacrylate as the polyfunctional agent but points out that Freeman et al does disclose the use thereof for cross-linking polymers and that the use of such an alternative polyfunctional agent would have been obvious.

Freeman et al is no more pertinent than the other references cited and relied upon. This patent discloses soft, improved flexible acrylic material for IOLs and the like. These materials contain two principal components: one arylacrylic hydrophobic monomer and one hydrophilic monomer. The remainder of the material may include additional components, such as cross-linking agents. This reference unlike the previous references does not concern making of an intraocular lens or other kinds of optical lens, part of which is made of a soft foldable material and part of which is made of a relatively rigid material. Indeed, the materials used in the Freeman et al patent are exclusively for producing lenses of soft foldable material. This is of no import as a polyfunctional agent for a flexible material used in an intraocular lens that this patent discloses diethylene glycol dimethacrylate.

In view of the present amendment and the foregoing remarks, it is believed that this application has been placed in condition for allowance.

In the event that there are any questions relating to this amendment, it would be appreciated if the Examiner would telephone the undersigned attorney.

Respectfully submitted,

YOUNG & THOMPSON ,

Attached hereto is a marked-up version of the changes made to the specification. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,

YOUNG & THOMPSON

By _____

Robert J. Patch
Attorney for Applicants
Registration No. 17,355
745 South 23rd Street
Arlington, VA 22202
Telephone: 703/521-2297

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Page 10, the paragraph beginning on line 31, bridging page 11, has been replaced as follows:

--The process of the invention for structural modification by selective rigidification, described above, makes it possible to obtain implants featuring haptic parts having attachment members of various geometric shapes, attachment members having damping elements, or flat haptic parts or other haptic parts of any desired configuration. The haptic parts of the intraocular implants of Figs. 1 and 2 comprise attachment members.--